

# COPY

Docket No: 33,383-00

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of: Randall K. Holmes et al.

Serial No.: 09/806,370 Group Art No.: To be Assigned

Filed: September 30, 1999 Examiner: To be Assigned

For: Mutant Cholera Holotoxin as an Adjuvant

Confirmation No.: 8568

Customer Number: 25291

Commissioner for Patents  
Box DD  
Washington, DC 20231

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In accordance with 37 CFR 1.97 and 1.98, Applicants submit herewith patents, publications, or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) the information is material to the examination of this application; (iii) additional information material to the examination of this application does not exist; (iv) the information, protocols, results and the like reported by third parties are accurate or enabling; or (v) the information constitutes prior art to the subject invention.

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I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number ET334776318US addressed to the Commissioner for Patents, Box DD, Washington, DC 20231.

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Alan M. Gordon

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- a.  is filed within three months of the filing date of the application.
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- c.  is filed before the mailing date of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- d.  is filed after the period specified in 2(a), 2(b) or 2(c) above, but before the mailing date of a final action under 37 CFR 1.311. This statement includes a certification under 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p).
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4.  Newly Cited Information

A legible copy of the patents, publications or other information cited on the attached form PTO 1449 is enclosed, except that no copy of a pending U.S. application is enclosed.

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Prior application is Serial Number , filed on for

6.  Concise Explanation  
Documents cited above which are not in the English Language  
a.  have been explained in the specification.  
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*Alan M. Gordon*  
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Substitute for form 144B/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)				Complete if Known	
Sheet		1	of	1	Application Number Filing Date First Named Inventor Group Art Unit Examiner Name
					09/806370 September 30, 1999 Randall K. Holmes
					Attorney Docket Number
					33,383-00

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number (If known)	Kind Code (If Known)			
✓	1.	5182109		Tamura	01-26-1993	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (If Known)				
✓	2.	PCT	WO 93/13202		Domenighini	07-08-1993		<input type="checkbox"/>
✓	3.	PCT	WO 96/06627		Clements	03-07-1996		<input type="checkbox"/>
✓	4.	PCT	WO 97/02348		Pizza	01-23-1997		<input type="checkbox"/>
✓	5.	PCT	WO 97/05267		King	02-13-1997		<input type="checkbox"/>
✓	6.	PCT	WO 98/45324		McGhee	10-15-1998		<input type="checkbox"/>
✓	7.	PCT	WO 97/29771		Fontana	08-21-1997		<input type="checkbox"/>
✓	8.	PCT	WO 98/32461		Clements	07-30-1998		<input type="checkbox"/>
✓	9.	PCT	WO 98/42375		Barchfeld	10-01-1998		<input type="checkbox"/>

### OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T
		Author	Title	
✓	10.	JOBLING, MICHAEL G.	Analysis of the Structure and Function of Cholera Toxin A Subunit, Abstracts of the General Meeting-1991, American Society for Microbiology, p. 59, Abstract No. B-205.	<input type="checkbox"/>
	11.	GLINEUR, CORINE	Importance of ADP-Ribosylation in the Morphological Changes of PC12 Cells Induced by Cholera Toxin, Infection and Immunity, Oct. 1994, pp. 4176-4185, Vol. 62, No. 10.	<input type="checkbox"/>
✓	12.	LYCKE, N.	Strong Adjuvant Properties of Cholera Toxin on Gut Mucosal Immune Responses to Orally Presented Antigens, Immunology, 1986, pp. 301 - 308, Vol. 59.	<input type="checkbox"/>
✓	13.	MCKENZIE, SARA J.	Cholera Toxin B Subunit as a Carrier Protein to Stimulate a Mucosal Immune Response, The Journal of Immunology, October 1984, pp. 1818 - 1824, Vol. 133. No. 4.	<input type="checkbox"/>
✓	14.	MEKALANOS, JOHN J.	Cholera Toxin Genes: Nucleotide Sequence, Deletion Analysis and Vaccine Development, Nature, December 8, 1983, pp. 551 - 557, Vol. 306.	<input type="checkbox"/>
✓	15.	NEDRUD, JOHN	Oral Immunization Against Respiratory Viruses in Mice, Advances in Mucosal Immunology, 1995, Vol. 371B, pp. 1595 - 1598.	<input type="checkbox"/>
✓	16.	ELSON, CHARLES O.	Generalized Systemic and Mucosal Immunity in Mice After Mucosal Stimulation with Cholera Toxin, The Journal of Immunology, June 1984, pp. 2736 - 2741, Vol. 132, No. 6.	<input type="checkbox"/>
✓	17.	ELSON, CHARLES O.	Cholera Toxin Feeding Did Not Induce Oral Tolerance in Mice and Abrogated Oral Tolerance to an Unrelated Protein Antigen, The Journal of Immunology, December 1984, pp. 2892 - 2897, Vol. 133, No. 6.	<input type="checkbox"/>
✓	18.	RICHARDS, C.M.	Enhancement of the Immune Response to Non-replicating Herpes Simplex Virus Type-1 Preparations by Mucosal Administration in the Presence of Cholera Toxin, Vaccine, 1997, pp. 1065 - 1069, Vol. 15, No. 10.	<input type="checkbox"/>
✓	19.	YAMAMOTO, SHINGO	Mutants in the ADP-ribosyltransferase Cleft of Cholera Toxin Lack Diarrheogenicity but Retain Adjuvanticity, J. Exp. Med., April 7, 1997, pp. 1203-1210, Vol. 185, No. 7.	<input type="checkbox"/>

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.